

**Medikal Oluşum San. ve Tic. Ltd. Şti.**

## EC DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III

**Manufacturer:** Medikal Oluşum San. ve Tic. Ltd. Şti.

**Adress:** Dağyaka Mahallesi 2038. Cadde Selpa Sanayi Sitesi No:4 Blok: 20/2, 06980 Kahramankazan/Ankara/TURKEY

**Products:** Biohazard Autoclave Baq 19/24, Biohazard Baq 19/24.

**Classification:** Other device (all devices except Annex II and self-testing devices)

**We herewith declare that the above mentioned product meets the provisions of the council directive 98/79/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.**

**Medikal Oluşum San. ve Tic. Ltd. Şti. considers following laws, rules and standards:**

• **Directive 98/79/EC**

In-vitro-Diagnostica

• **EN ISO 14971**

Medical devices – Application of riskmanagement to medical devices

• **DIN EN ISO 13485**

Qualitysystems – Medical devices – Particular requirements for the application of EN ISO 9001

Ankara, 29.03.2017

Medikal Oluşum San. ve Tic. Ltd. Şti.

**MOS LAB®**  
**MEDİKAL OLUŞUM SANAYİ VE TİC. LTD. ŞTİ.**  
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Certified manufacturer  
according to ISO 9001  
and ISO 13485

ISO ISO  
13485 9001

MEDICAL DEVICES  
QUALITY  
MANAGEMENT

QUALITY  
MANAGEMENT

Berna Başhan  
General Manager